UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

Karen L. Bartlett

v.

Civil No. 08-cv-358-JL
Opinion No. 2010 DNH 123

Mutual Pharmaceutical Company, Inc.

MEMORANDUM ORDER

This products liability case presents numerous disputes over the admissibility of expert testimony. Plaintiff Karen Bartlett, who took the generic drug Sulindac and suffered severe side effects, brought suit against the drug's manufacturer, Mutual Pharmaceutical Company, asserting state-law claims of strict products liability and negligence based on defective design. She alleges, in particular, that Sulindac's safety risks outweigh its medical benefits, making it an unreasonably dangerous product. This court has subject-matter jurisdiction under 28 U.S.C. § 1332(a)(1) (diversity), because Bartlett is a New Hampshire citizen and Mutual is located in Pennsylvania.

Earlier in the case, this court denied Mutual's motion for judgment on the pleadings, see Fed. R. Civ. P. 12(c), rejecting the argument that Bartlett's claims were pre-empted by federal law. Bartlett v. Mut. Pharm. Co., 659 F. Supp. 2d 279 (D.N.H. 2009). After discovery, both parties moved for summary judgment. See Fed. R. Civ. P. 56. This court recently granted each of

their motions in part, eliminating several claims and defenses, but allowing Bartlett to proceed to trial on her defective design claims. Bartlett v. Mut. Pharm. Co., 2010 DNH 112.

Both parties have now moved to exclude or limit the testimony of each other's expert witnesses at the upcoming trial. See Fed. R. Evid. 702. After reviewing their submissions, this court grants the motions in part and denies them in part. The parties' experts have sufficient qualifications and a sufficient foundation to support most of their proffered opinions. But they may not offer legal opinions that impinge upon the roles of the judge and jury, nor may they speculate about what the Food & Drug Administration ("FDA") would have done in hypothetical circumstances.

I. Applicable legal standard

"The touchstone for the admission of expert testimony in federal court litigation is Federal Rule of Evidence 702." Crowe v. Marchand, 506 F.3d 13, 17 (1st Cir. 2007). Rule 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. As the structure of this rule suggests, before the jury can consider expert testimony over the adverse party's objection, the trial judge, serving as "gatekeeper," must determine whether the testimony has a proper foundation. See, e.g., Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 597 (1993). The party introducing the testimony bears the burden of proving its admissibility. Id. at 592. "Rule 702 has been interpreted liberally in favor of the admission of expert testimony." Levin v. Dalva Bros., Inc., 459 F.3d 68, 78 (1st Cir. 2006).

While presented as Rule 702 challenges, many of the parties' requests would be more accurately described as motions in limine, since they seek to exclude testimony for lack of relevance rather than lack of foundation. Like all evidence, expert testimony must be relevant to the issues in the case. See, e.g., United States v. Pena, 586 F.3d 105, 110 (1st Cir. 2009). Evidence is relevant if it has "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Fed. R. Evid. 401. The relevance standard is also interpreted liberally. See, e.g., Mitchell v. United States, 141 F.3d 8, 14 (1st Cir. 1998).

II. Background

The factual and procedural background of this case is set forth in the recent summary judgment ruling, Bartlett, 2010 DNH 112, at 3-8, and need not be repeated here.

III. Analysis

A. *Bartlett's motion*

Bartlett has made 37 requests to exclude or limit testimony by Mutual's experts. Some of her requests will be analyzed together, since they involve closely related issues.

i. Generic drug labeling (Requests 1-8, 22, 29-30)

The first issue raised by Bartlett's motion is whether Mutual's experts may testify about federal law, FDA policy and procedure, or industry practice with regard to generic drug labeling.[1] This court has already ruled that federal law allows generic drug manufacturers to strengthen a generic drug's safety warning unilaterally. See Bartlett, 659 F. Supp. 2d at 302. But

[1]Although this court recently granted summary judgment to Mutual on Bartlett's failure-to-warn claims, Sulindac's label is still relevant to this case in at least one respect, which is that Mutual's "comment k" defense depends on the adequacy of the product's warning, among other things. See Bartlett, 2010 DNH 122, at 26 (discussing Restatement (Second) of Torts § 402A, cmt. k (1965)). This court will therefore resolve all of the expert challenges relating to Sulindac's label, without prejudice to any trial objections challenging the relevance of such evidence in light of this court's summary judgment ruling.

Mutual's experts intend to testify that such changes would be inconsistent with the "real-life" FDA policy and industry practice, which is for only the manufacturer of the brand-name or "reference listed" drug to make such changes. Bartlett argues that this testimony must be excluded from trial because it would be contrary to this court's legal ruling and thus confusing to the jury.

Since "it is the judge's role, not a witness's, to instruct the jury on the law," this court "has broad discretion to exclude expert opinion evidence about the law that would impinge on the roles of the judge and the jury" or would cause "jury confusion." Pelletier v. Main St. Textiles, LP, 470 F.3d 48, 54-55 (1st Cir. 2006). Indeed, "[e]xpert testimony proffered solely to establish the meaning of a law is presumptively improper." United States v. Mikutowicz, 365 F.3d 65, 73 (1st Cir. 2004); see also Nieves-Villanueva v. Soto-Rivera, 133 F.3d 92, 99 (1st Cir. 1997). And even if such testimony has independent factual significance, i.e., aside from the content of the law, it still may be excluded "if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury." Fed. R. Evid. 403; see also United States v. Ahrendt, 560 F.3d 69, 76 (1st Cir. 2009).

As an initial matter, Mutual concedes that its experts cannot and will not "provide testimony that interprets any

statutes or regulations." This concession is well taken. Again, such testimony would be presumptively improper. See Mikutowicz, 365 F.3d at 73. It would also be unfairly prejudicial to Bartlett and confusing to the jury, because it would conflict with this court's legal rulings and, presumably, its jury instructions. Since Mutual has not opposed that part of Bartlett's request, it is granted. No defense experts may testify about the meaning or applicability of the law. See Fed. R. Evid. 403; Pelletier, 470 F.3d at 54-55 (affirming exclusion of expert testimony regarding applicability of federal workplace safety regulations).

Mutual argues that, so long as its experts steer clear of the actual statutes and regulations, they should be allowed to testify about FDA policy and procedure. But such testimony raises many of the same concerns, because it is based largely on FDA documents that analyze or parrot the language of the relevant statutes and regulations. Indeed, they are some of the very same documents that this court interpreted in its earlier ruling. See, e.g., Bartlett, 659 F. Supp. 2d at 293 n.19 (rejecting Mutual's interpretation of 2004 industry guidance); id. at 294 n.21 (rejecting Mutual's interpretation of "the FDA's remarks in proposing and promulgating these regulations"). The testimony is thus a roundabout way of challenging this court's ruling. As such, it creates the same danger of undue prejudice and confusion

as testimony about the statutes and regulations themselves. See Fed. R. Evid. 403.

Moreover, Mutual's experts have not pointed to any evidence of the supposed policy in action, so their testimony about it amounts to little more than "speculation as to what FDA might have done in hypothetical circumstances." In re Rezulin Prods. Liab. Litig., 309 F. Supp. 2d 531, 550 (S.D.N.Y. 2004) (excluding such speculation). Both parties seem to agree that there is no historical evidence, at least in this record, that the FDA has either accepted or rejected previous attempts by generic drug manufacturers to unilaterally strengthen a drug warning. So the policy is not based on what the FDA has actually done; rather, it is based on what the FDA purportedly believed or would have done, according to former FDA officials. Such testimony is not sufficiently reliable to satisfy Rule 702(2).

If Mutual had "simply no other practical means to prove the point," then this court might be more inclined to admit the testimony about FDA policy and procedure, despite its problems. United States v. Fields, 871 F.2d 188, 198 (1st Cir. 1989); see also United States v. Scott, 270 F.3d 30, 51 (1st Cir. 2001) (noting that the "availability of other means of proof" is an "appropriate factor" to consider in determining whether evidence should be excluded). But that is not the case. Mutual can make its point effectively through testimony about industry practice,

without needing to try to cast it as a matter of FDA policy and procedure. Specifically, Mutual's experts can testify that the longstanding industry practice is for the manufacturer of the brand-name or "referenced listed" drug to make changes to the drug's label, and for generic manufacturers simply to parrot any such changes.

Bartlett argues that testimony about industry practice is also unduly prejudicial and confusing to the jury. But this court disagrees. "[I]n general, the customs and practices of an industry are proper subjects for expert testimony." Pelletier, 470 F.3d at 55. The jury is fully capable of understanding that there may be a gap between what the law requires and what industry members actually do. Indeed, conformity with industry practice is not an absolute defense to liability under New Hampshire law, because "entire industries may lag behind" the standard of care. Heath v. Sears, Roebuck & Co., 123 N.H. 512, 530 (1983). But it is nonetheless a factor that the jury may consider in evaluating strict liability claims, see, e.g., Thibault v. Sears, Roebuck & Co., 118 N.H. 802, 814 (1978), and negligence claims, see, e.g., 8 Richard B. McNamara, New Hampshire Practice § 4.74, at 4-107 (3d ed. 2003).

In sum, this court concludes that Mutual's experts may not testify about federal law (whether directly or under the guise of FDA policy and procedure) on the issue of whether a generic

manufacturer has the ability or responsibility to strengthen a generic drug's safety warning. The probative value of such testimony is substantially outweighed by the danger of unfair prejudice and jury confusion. See Fed. R. Evid. 403. Witnesses may, however, testify about industry practice in that regard.

ii. Late production of prior transcript (Request 9)

The next issue is whether Dr. Stewart Ehrreich, designated by Mutual as a pharmacological expert, should be precluded from testifying altogether because Mutual failed to produce (until the day of his deposition) a transcript from a deposition he gave in another case, where he testified that the label for ibuprofen was inadequate because it did not mention the possibility of death. According to Bartlett, the parties had agreed that any such transcripts would be produced at least seven days before Dr. Ehrreich's deposition. Mutual, however, denies that any such agreement existed (or that Bartlett complied with it for her own experts, see Part III.B.i, infra). According to Mutual, Dr. Ehrreich "simply forgot" about that prior deposition, and Bartlett suffered no prejudice because Dr. Ehrreich testified about it anyway.

Whether an agreement actually existed between the parties is unclear from the record. Mutual proposed a schedule in which transcripts of Dr. Ehrreich's prior depositions would be produced

seven days in advance of his deposition in this case, but the record contains no written acceptance of this proposal by Bartlett, and Mutual denies reaching agreement. In any event, even if an agreement existed, Bartlett has not suffered any prejudice from the late production. At his deposition in this case, Dr. Ehrreich testified in detail about the earlier case and the specific opinions that he gave there. Bartlett's counsel thus had an adequate opportunity to explore that issue. Under the circumstances, it would be inappropriate to exclude Dr. Ehrreich from testifying. See Fed. R. Civ. P. 37(c)(1) (providing for exclusion of expert witness due to untimely disclosures "unless the failure was substantially justified or harmless").

iii. References to "bad luck" (Request 10)

Bartlett argues that no defense expert should be allowed to characterize her injuries as "bad luck," "luck of the draw," or any similar description, which in her view is an "advanced" expert opinion that lacks a proper foundation. It is true that the word "luck" could have a more advanced connotation in this context, with more specific implications (i.e., that Bartlett's injuries were entirely random side effects of Sulindac, unrelated to her physical traits or any other nonrandom factors). But Mutual's experts seem to be using it in a less advanced way, as a

shorthand for saying that only a very small percentage of the people who have taken Sulindac have suffered SJS/TEN as a side effect. That is a probative fact for which, on the record before the court, it appears that a proper foundation has been laid under Rule 702.

Nevertheless, there is some risk that the jury, upon hearing an expert describe Bartlett's injuries as "bad luck" or "luck of the draw," might be misled into thinking that the expert intends the more advanced, implicative meaning, for which a proper foundation appears not to have been laid under Rule 702. While that risk is not very high, the probative value of the word "luck" is even lower. Mutual's experts can make the same point using other words that avoid any risk of unfair prejudice. Bartlett's request to exclude defense experts from using the word "luck" in reference to her injuries is therefore granted.[2] See Fed. R. Evid. 403.

iv. Filling of prescription (Requests 11-13)

Next, Bartlett challenges three of Dr. Ehrreich's opinions

[2]This ruling is limited to expert testimony. Depending on the context, such language may be permissible in closing argument, where counsel is generally given "some leeway to comment on the evidence." Gomes v. Brady, 564 F.3d 532, 538 (1st Cir. 2009); see also Lewis v. City of Chicago Police Dep't, 590 F.3d 427, 444 (7th Cir. 2009). Coming from an attorney rather than an expert, the word "luck" does not carry the same risk of unfair prejudice.

about the filling of her Sulindac prescription: (1) that the pharmacy could have filled the prescription with another manufacturer's version of the drug; (2) that the pharmacy "likely" filled the prescription with Mutual's version because it was the cheapest; and (3) that Bartlett would have suffered the same injuries if she took one of the other versions, since they all had the same active ingredients. Bartlett argues that all of these opinions are speculative. She is right as to the second one; Dr. Ehrreich admitted in his expert report that the pharmacy's reason for choosing Mutual's version "is not known." Bartlett's request to exclude that opinion is therefore granted. See Fed. R. Evid. 702(1).

But the other two opinions have a sufficient foundation. Indeed, the first one is consistent with the testimony of Bartlett's doctor, who wrote the prescription. And the third one is based on the fact that the FDA requires all versions of a drug to have the same active ingredients. Bartlett notes that it is theoretically possible that her injuries were caused by Sulindac's inactive ingredients, which need not be identical. But Dr. Ehrreich made clear that his opinion was based on the assumption that the active ingredients caused Bartlett's injuries, which he understood to be one of her allegations. Bartlett has not disclaimed that understanding of her claims or identified any evidence to the contrary. See Levin, 459 F.3d at

79 ("an expert may offer opinions based on assumptions that are not contrary to the evidence at trial"). Bartlett's request to exclude those opinions is therefore denied.[3]

v. Number of NSAID users (Request 14)

Bartlett requests that another defense expert, dermatologist Robert Stern, be precluded from testifying about the number of people in the United States who have used NSAIDs. She argues that such testimony, which Dr. Stern derived from FDA materials, is hearsay and is not relevant. But "expert opinions based on otherwise inadmissible hearsay" may be admitted if the underlying "facts or data are 'of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject.'" Daubert, 509 U.S. at 595 (quoting Fed. R. Evid. 703); see also United States v. Corey, 207 F.3d 84, 89 (1st Cir. 2000). The underlying "facts or data need not be admissible in order for the opinion or inference to be admitted." Fed. R. Evid. 703.

Experts in the field of medicine reasonably and routinely rely on FDA materials in forming their opinions on prescription drugs and their use in the United States. Thus, Dr. Stern's

[3]Bartlett's challenge to the relevance of such evidence will be considered in connection with her first motion in limine (document no. 185). The court expresses no opinion on that issue here.

opinion may be admitted even if it is based on hearsay. Furthermore, the number of NSAID users is relevant contextual evidence for evaluating whether Sulindac is unreasonably dangerous. See, e.g., First Marblehead Corp. v. House, 541 F.3d 36, 42 (1st Cir. 2008) ("Testimony that provides a necessary context and framework ... can be appropriate for expert testimony."); see also Fed. R. Evid. 401, 402. Bartlett's request to exclude such testimony is denied.

vi. FDA awareness of SJS/TEN risks (Request 15)

Bartlett argues that Dr. Ehrreich should be precluded from testifying about the FDA's awareness of the SJS/TEN risks posed by NSAIDs because he left the agency many years ago, rendering any such opinion speculative. Actually, Dr. Ehrreich worked for the FDA from 1979 to 1986, and his opinion is that the FDA has been aware of the risks since the early 1980s, so his time at the agency overlaps with the period on which he is opining. But that is ultimately immaterial, because his testimony is based on express statements in FDA documents from the time period in question, not on mere extrapolation from his personal experience in an earlier era. On this record, his opinion appears to have a sufficient foundation under Rule 702(1). Bartlett's request to exclude the testimony is denied.

vii. Other NSAID safety warnings (Request 16)

The next issue is whether defense experts may testify about the safety warnings for NSAIDs other than Sulindac. Bartlett argues that such testimony should be allowed only if it relates to NSAIDs that were specifically evaluated by the FDA or removed from the market, because otherwise it is not relevant. Mutual argues, in response, that such testimony is relevant to whether Sulindac had an adequate warning. This court agrees with Mutual. While conformity with industry practice is not an absolute defense to liability under New Hampshire law, it is a relevant consideration in evaluating both products liability and negligence claims. See Thibault, 118 N.H. at 814; 8 McNamara, supra, § 4.74, at 4-107; see also Fed. R. Evid. 401, 402. Bartlett's request to confine such evidence to that which favors her position is denied.

viii. Undisclosed opinions (Request 17)

Bartlett requests a blanket ruling that no defense expert may testify at trial to any opinion not already set forth in his or her expert report. It is true that an expert's report "must contain ... a complete statement of all opinions the witness will express and the basis and reasons for them." Fed. R. Civ. P.

26(a)(2)(B)(I). And where "a party fails to provide information ... as required by Rule 26(a)," that party "is not allowed to use that information or witness to supply evidence ... at a trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1). But whether an untimely disclosure is substantially justified or harmless cannot be determined in the abstract; it depends on the particular circumstances.[4] This court therefore declines to issue a blanket ruling, but rather will resolve any such issues as they arise at trial in the context of their specific facts.

ix. Hypersensitivity warning (Requests 18-21)

The next issue is whether Drs. Stern and Ehrreich may testify that the hypersensitivity warning in the Sulindac label (quoted in Bartlett, 2010 DNH 112, at 5) served as an adequate warning of SJS/TEN. Bartlett argues that such testimony is beyond the scope of their expert reports and their expertise. Mutual appears to accept that Dr. Ehrreich cannot testify to that particular opinion, which he never properly disclosed, so Bartlett's request to exclude his testimony on this subject is

[4]There is also Rule 703's corollary--pertaining to the informational basis of expert opinion testimony--that such testimony may under some circumstances be based on facts "perceived by or make known to the expert at or before the hearing." Fed. R. Evid. 703 (emphasis added).

granted. But Mutual argues that Dr. Stern, as one of the world's leading experts on SJS/TEN, is well qualified to testify about the meaning and adequacy of the hypersensitivity warning and that he properly disclosed his opinion in his expert report.

Contrary to what Bartlett suggests, Dr. Stern's expert report made clear that, in his opinion, the Sulindac label's hypersensitivity warning and its reference to "severe skin reactions," coupled with its cross-reference to a list of adverse reactions that included SJS/TEN, served as an adequate warning that SJS/TEN were among the risks of taking Sulindac. Indeed, one of the headings in his report is: "The warning in the 2004 sulindac labeling was clear and consistent with the knowledge concerning the risk of severe skin reactions including Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis." Bartlett's argument that he failed to disclose that opinion in his report is unpersuasive.

Equally unpersuasive is Bartlett's argument that Dr. Stern lacks sufficient expertise to offer that opinion. Dr. Stern founded an international study of SJS/TEN, wrote some of the leading articles on their connection to NSAIDs (including one in the New England Journal of Medicine entitled "Severe adverse cutaneous reactions to drugs"), is the chief of dermatology at Beth Israel Deaconess Hospital in Boston, is a full-time professor of dermatology at Harvard Medical School, and has

chaired multiple FDA advisory committees on the safety and efficacy of drugs. See, e.g., Forrestal v. Magendantz, 848 F.2d 303, 308 (1st Cir. 1988) (affirming admission of doctor's expert testimony "based on his own knowledge and experience").

Bartlett argues that Dr. Stern should not be allowed to offer any opinions on Sulindac's label (including the hypersensitivity warning) because he stated at his deposition that "I'm not an expert on labeling." But Dr. Stern actually amended that statement in an errata sheet, adding the word "regs" at the end to clarify that he is not an expert on the FDA regulations applicable to drug labels. See Fed. R. Civ. P. 30(e)(1)(B) (allowing deponent to make "changes in form or substance" to his deposition transcript). That is a plausible interpretation of what he meant. While calling the correction a "sham," Bartlett has not moved to strike it. She is, of course, free to explore it on cross-examination. See, e.g., Daroczi v. Vt. Ctr. for the Deaf & Hard of Hearing, Inc., 2004 DNH 027 (Muirhead, M.J.) (citing 7 Moore's Federal Practice § 30.63[3] (3d. ed. 2003)).

In any event, it is Dr. Stern's qualifications, not his extemporaneous disclaimer, that determine the permissible scope of his testimony. Cf. Pineda v. Ford Motor Co., 520 F.3d 237, 245 (3d Cir. 2008) (allowing expert to testify about certain aspects of product's safety warning even though he denied being a

"warnings" expert, because he was an expert on the product in question). Dr. Stern is sufficiently "qualified to render an opinion regarding the completeness or accuracy of the [Sulindac] label based on his knowledge of the risks of [Sulindac] and his own clinical experience." In re Baycol Prods. Litig., 532 F. Supp. 2d 1029, 1064 (D. Minn. 2007); see also In re Rezulin, 309 F. Supp. 2d at 556; In re Diet Drugs Prods. Liab. Litig., No. MDL 1203, 2000 WL 876900, at *11-12 (E.D. Pa. June 20, 2000).

Bartlett also argues that Dr. Stern's testimony about the hypersensitivity warning is unreliable because in 2006, after the events at issue in this case, the FDA adopted a new label for Sulindac that included both a hypersensitivity warning and a new SJS/TEN warning in its "Warnings" section. See Bartlett, 2010 DNH 112, at 15 n.6. She reasons that the FDA would not have approved "side-by-side redundant and duplicative warnings" and therefore must believe that -- contrary to Dr. Stern's opinion -- the hypersensitivity language in the earlier label did not adequately warn of SJS/TEN. But Bartlett has not presented any authority or evidence to support that proposition (which is just as speculative as Mutual's excluded testimony about FDA beliefs, see Part III.A.i, supra). There is nothing inherently illogical about repeating a safety warning, especially when one wants to emphasize a point.

And in any event, an expert's opinion need only be "based

upon sufficient facts or data," Fed. R. Evid. 702(1), not perfectly consistent with every piece of available evidence. Emphasizing inconsistencies between an expert's opinions and the evidence, of course, is one of the principal purposes of expert cross-examination. Bartlett's request to exclude Dr. Stern's testimony about the warning is denied.

x. Other NSAID side effects (Request 23)

The next issue is whether defense experts may testify about other NSAID side effects that Bartlett never suffered, such as gastrointestinal problems. Bartlett argues that such testimony is not relevant. But it is highly relevant to determining whether Sulindac's safety risks outweigh its medical benefits, making it an unreasonably dangerous product. See, e.g., Price v. BIC Corp., 142 N.H. 386, 389 (1997) (noting that whether a product is unreasonably dangerous "is determined by the jury using a risk-utility balancing test"); see also Fed. R. Evid. 401, 402. The jury is not limited to considering only the side effects that Bartlett suffered. Bartlett's request to exclude such testimony is denied.

xi. Impact on FDA and industry (Requests 24-25)

Bartlett seeks to preclude Dr. Ehrreich from testifying that

if generic drug manufacturers were each responsible for monitoring the safety of their drugs or strengthening their warnings, they would either have to raise prices or go out of business, and that the FDA would be over-burdened. This court has already ruled, as a matter of federal law, that generic manufacturers are indeed responsible for such safety surveillance, see Bartlett, 2010 DNH 112, at 29-31 (citing 21 C.F.R. § 314.80(b)), and for the content of their drugs' warnings, see id. at 9 n.4 (citing 21 C.F.R. § 201.57(e)). Mutual's experts may not suggest otherwise, either expressly or implicitly. To that extent, Bartlett's request is granted. See Fed. R. Evid. 403.

xii. Rebuttal of Bartlett's experts (Requests 26-28)

Bartlett argues that Dr. Ehrreich should not be allowed to criticize Bartlett's experts without first identifying the specific opinions with which he is disagreeing. She notes, for example, that Dr. Ehrreich's report launched a number of broadsides against her expert Dr. Randall Tackett's report, calling it "disturbing" and claiming to be "shocked and dismayed" by the amount of "misinformation." While Dr. Ehrreich's specific disagreements with Bartlett's experts and the basis of those disagreements are relevant and admissible evidence (assuming they have a proper foundation), the extent to which he is "disturbed"

or "shocked and dismayed" by Bartlett's expert opinions and his pejorative characterizations of them are not. See, e.g., United States v. Gonzalez-Maldonado, 115 F.3d 9, 16 (1st Cir. 1997) (expert opinion on another witness's credibility "is ordinarily inadmissible pursuant to Rule 702"); see also Ramirez v. Debs-Elias, 407 F.3d 444, 447-49 (1st Cir. 2005). Bartlett's request to exclude such comments is granted.

Bartlett also argues that Dr. Ehrreich should be precluded from expressing two particular opinions that purport to rebut arguments that Bartlett's expert Dr. Tackett never made: one relating to so-called "black box" warnings, and the other relating to "due diligence." In both instances, Dr. Ehrreich's characterization of Dr. Tackett's opinion is not quite accurate. Dr. Tackett opined that Mutual should have advocated to the FDA for a "black-box" warning, not (as Dr. Ehrreich says) that Mutual should have implemented one unilaterally. And Dr. Tackett opined that Mutual should have conducted "due diligence" before filing its initial application to manufacture Sulindac, not afterward (as Dr. Ehrreich says). Accordingly, this court grants Bartlett's request to exclude the inaccurate comments.

xiii. Industry standards of care (Request 31)

The next issue is whether Dr. Ehrreich may testify about

standards of care within the pharmaceutical industry. Bartlett argues that such testimony should be prohibited unless her own experts may also testify about those standards, because Dr. Ehrreich is no more qualified than they are and because he provided no foundation for his opinions. But one party's failure to disclose an expert opinion on a given issue has little or no bearing on the admissibility of an adverse party's properly disclosed expert opinion evidence on that issue. Cf. Adams v. J. Myers Builders, 2009 DNH 181, 18 n.7. Whether Dr. Ehrreich's testimony may be admitted depends on his own qualifications, not on whether Bartlett's experts would be qualified to opine on the same issues.

As a pharmacologist who has held high-ranking jobs with the FDA and three major drug companies, Dr. Ehrreich is sufficiently qualified to testify about the standards of care within that industry. The foundation for that testimony is his own experience. See, e.g., Forrestal, 848 F.2d at 308 (affirming admission of doctor's expert testimony "based on his own knowledge and experience"); Fed. R. Evid. 702, advisory committee notes (2000) (noting that "the text of Rule 702 expressly contemplates that an expert may be qualified on the basis of experience," which may be "the predominant, if not sole, basis for a great deal of reliable expert testimony"). Bartlett's request to exclude the testimony is denied.

xiv. Knowledge in medical community (Requests 32-35)

Bartlett argues that Dr. Stern should be precluded from testifying about what doctors generally know about SJS/TEN and their link to NSAIDs, because such testimony is speculative. Indeed, most courts have prohibited experts from testifying "about what all doctors generally consider in making prescription decisions" or about "what doctors generally think," unless the testimony is based on something more reliable than simply the expert's own experience as a doctor. In re Diet Drugs, 2000 WL 876900, at *11-12; see also, e.g., In re Baycol, 532 F. Supp. 2d at 1064; Pfizer Inc. v. Teva Pharms. USA, Inc., 461 F. Supp. 2d 271, 277 (D.N.J. 2006); In re Rezulin, 309 F. Supp. 2d at 556. Since Dr. Stern has not identified a more reliable basis, Bartlett's request to exclude his testimony about what doctors generally know is granted. See Fed. R. Civ. P. 26(a)(2)(B); Fed. R. Evid. 702.

Dr. Stern may, however, testify about what a reasonable doctor should know about the link between NSAIDs and SJS/TEN and how a reasonable doctor would interpret Sulindac's safety warning. Such testimony is properly based on his experience as a professor of dermatology at Harvard Medical School, the chief of dermatology at a major Boston hospital, and the author of frequently cited articles on SJS/TEN and its link to NSAIDs. See Fed. R. Evid. 702; First Marblehead, 541 F.3d at 42 (upholding

admission of a financial expert's testimony on how a reasonable investor would have analyzed stock options).

xv. Dr. Valuck (Request 36)

Bartlett seeks to exclude the testimony of another defense expert, pharmacology professor Dr. Robert Valuck, on the grounds that he was allegedly unprepared for his deposition. In particular, Bartlett emphasizes that Dr. Valuck erroneously stated that there were no Sulindac cases in a particular SJS/TEN study on which he opined, when in fact there was one such case. But this error (assuming it was one) resulted from a discrepancy between the print and online versions of the study. Dr. Valuck relied on the print version, which listed no Sulindac cases, whereas the online version listed one case. At his deposition, Dr. Valuck made clear that regardless of which version of the study is correct, it would not change his opinions.

Moreover, Bartlett has the ability to explore Dr. Valuck's error (if any) and its impact (if any) through cross-examination. "It is not the job of the court to insure that [expert testimony] is error-free" -- only that it has a sufficiently reliable foundation to satisfy Rule 702. Southwire Co. v. J.P. Morgan Chase & Co., 528 F. Supp. 2d 908, 928 (W.D. Wis. 2007). Because Dr. Valuck's testimony about the SJS/TEN study appears, on this

record, to have a proper foundation, Bartlett's request to exclude his testimony is denied.

xvi. Dr. Duffy (Request 37)

Finally, Bartlett argues that the testimony of Mutual's economic expert, Dr. Martin Duffy, should be excluded because he used the wrong figure for the cost of Bartlett's eye surgeries, thus rendering all of his computations unreliable. Mutual concedes that Dr. Duffy accidentally imported the wrong figure from the report of another defense expert, Dr. Jane Mattson, but argues that Dr. Duffy's economic methodology is nonetheless reliable and that he should be allowed to testify using the corrected figures.

The general rule is that an expert's minor computational errors go to the weight of his testimony, rather than to its admissibility. See, e.g., In re Scrap Metal Antitrust Litig., 527 F.3d 517, 530 (6th Cir. 2008); see also In re Pharm. Indus. Avg. Wholesale Price Litig., 582 F.3d 156, 198 (1st Cir. 2009) (affirming admission of expert's testimony, even if he made "small" errors, because they did not affect "the reliability of his damages calculation"). Indeed, in a case involving this same expert, our court of appeals ruled that "whatever shortcomings existed in Duffy's calculations went to the weight, not the

admissibility, of the testimony." Cummings v. Std. Register Co., 265 F.3d 56, 65 (1st Cir. 2001). The same reasoning applies here. Dr. Duffy's error is unrelated to his methodology and easy for him to correct in his trial testimony (or to expose on cross-examination if he does not). Bartlett's request to exclude him from testifying is denied.

B. *Mutual's motion*

For its part, Mutual seeks to exclude or limit the testimony of Bartlett's expert witnesses on various grounds and also to exclude any expert testimony by Bartlett's treating physicians. This court will address each request in turn (identifying them by the section of Mutual's motion in which they were raised).

i. Failure to produce prior transcripts (Request A)

The first issue raised by Mutual's motion is whether three of Bartlett's experts should be precluded from testifying because Bartlett failed to produce their prior deposition transcripts from other cases. This is essentially the mirror image of Bartlett's request to exclude one of Mutual's experts, Dr. Ehrreich, from testifying due to the late production of such a transcript. See Part III.A.ii, supra. This court denied Bartlett's request and, for similar reasons, denies Mutual's

request as well. It is not clear from the record that Bartlett violated any disclosure obligations, and even if she did, exclusion would be an inappropriate sanction under the circumstances. See Fed. R. Civ. P. 37(c)(1) (providing for exclusion of expert witness for failure to disclose, "unless the failure was substantially justified or harmless").

ii. Similarity of experts' reports (Request A)

Mutual also argues that two of Bartlett's experts, pharmacologist Dr. Randall Tackett and burn surgeon Dr. Roger Salisbury, should be precluded from testifying because their reports contain such similar language that both reports must have been prepared by Bartlett's counsel, not by the experts themselves. Mutual argues that this is a violation of Fed. R. Civ. P. 26(a)(2)(B), which requires each party's expert disclosures to "be accompanied by a written report ... prepared and signed by the witness." Bartlett argues, in response, that the reports are "99 percent textually distinct" and contain similar language in only a few areas where the two experts have shared experiences and expertise.

It is well established that "Rule 26(a)(2)(B) does not preclude counsel from providing assistance to experts in preparing reports, and indeed," in some complex cases, "this

assistance may be needed." Fed. R. Civ. P. 26(a)(2)(B), advisory committee notes (1993). The report, however, must be based on the expert's prior substantive input, must reflect the testimony to be given by the witness, and must be signed by the witness. Id.; see also United States v. Kalymon, 541 F.3d 624, 637-38 (6th Cir. 2008); Jenkins v. Bartlett, 487 F.3d 482, 488 (7th Cir. 2007); Crowley v. Chait, 322 F. Supp. 2d 530, 543 (D.N.J. 2004). Here, both experts' reports satisfy those requirements. Mutual's request to exclude their testimony under Rule 26(a)(2)(B) is denied.

iii. FDA regulations (Requests B.1-2)

The next issue raised by Mutual's motion is whether Bartlett's experts may testify about the meaning or applicability of FDA regulations and whether Mutual violated them. Such opinions appear frequently in Dr. Tackett's report and, to a lesser extent, in Dr. Salisbury's report. As discussed in Part III.A.i, supra, this court has "broad discretion to exclude expert opinion evidence about the law that would impinge on the roles of the judge and the jury." Pelletier, 470 F.3d 48, 54-55. Indeed, "[e]xpert testimony proffered solely to establish the meaning of a law is presumptively improper." Mikutowicz, 365 F.3d at 73.

Bartlett seems to believe that these principles apply only when the expert is wrong about the law, but that is not so. They apply even when the expert is right. See, e.g., Nieves-Villanueva, 133 F.3d at 100 ("the judge's expert knowledge of the law makes any such assistance at best cumulative, and at worst prejudicial") (emphasis added). Mutual's request to exclude such testimony is therefore granted. See Fed. R. Evid. 403. If Bartlett wants the jury to know what relevant FDA regulations require, she can propose appropriate jury instructions. And if she wants to show the jury that Mutual violated them, she may do so by introducing evidence of Mutual's acts or failures to act, rather than conclusory opinions from her experts.

iv. Calling Mutual "negligent" (Request B.3)

A related issue is whether Bartlett's experts may describe Mutual's conduct as "negligent," which they repeatedly do in their expert reports. The general rule is that "testimony in the form of an opinion or inference otherwise admissible is not objectionable because it embraces an ultimate issue to be decided by the trier of fact." Fed. R. Evid. 704(a). But that rule "does not vitiate the rule against expert opinion on questions of law." Nieves-Villaneuva, 133 F.3d at 100. Nor is it "a carte blanche for experts to substitute their views for matters well within the ken of the jury." Dinco v. Dylex Ltd., 111 F.3d 964,

973 (1st Cir. 1997).

Courts have generally prohibited experts from using the term "negligent" to describe the defendant's conduct in a negligence case where the opposing party objects to it. See 4 Weinstein's Federal Evidence § 704.04[1], at 704-10 (2d ed. 1997) (citing Andrews v. Metro N. Commuter R.R., 882 F.2d 705, 708 (2d Cir. 1989), and Owen v. Kerr-McGee Corp., 698 F.2d 236, 240 (5th Cir. 1983)); see also Persinger v. Norfolk & W. Ry. Co., 920 F.2d 1185, 1189 (4th Cir. 1990); Shahid v. City of Detroit, 889 F.2d 1543, 1547 (6th Cir. 1989). In light of Mutual's objection, Bartlett's experts may not use that term at trial to describe Mutual's conduct.

v. Qualifications (Request C)

Mutual also argues that Drs. Tackett and Salisbury lack sufficient expertise to testify about drug labeling and FDA regulatory procedures, because neither has ever worked for the FDA or a drug manufacturer, and both misused FDA terminology at their depositions. "It is not required," however, "that experts be 'blue-ribbon practitioners' with optimal qualifications." United States v. Vargas, 471 F.3d 255, 262 (1st Cir. 2006) (affirming admission of fingerprint expert's testimony even though he could not answer certain questions about fingerprint

characteristics). They need only be sufficiently "qualified ... by knowledge, skill, training, or education" to offer a reliable opinion. Fed. R. Evid. 702.

Dr. Tackett easily meets that standard. He has been a pharmacologist for more than 30 years, is a professor of pharmacology at the University of Georgia (where he has offered classes on FDA regulations and even conducted workshops for FDA employees), and has worked as a research investigator for various drug manufacturers. He also recently received a grant from a group of state Attorneys General to educate health care professionals about how to evaluate drug information. As another federal court recently concluded in allowing Dr. Tackett to testify, this "extensive experience" is enough to qualify him as an expert in this area. Lofton v. McNeil Consumer & Specialty Pharms., 05-cv-1531, 2008 WL 4878066, at *9 (N.D. Tex. July 25, 2008).

Dr. Salisbury's qualifications make for a closer call. He is certainly well qualified to testify about SJS/TEN by virtue of his 36 years as a burn surgeon and his treatment of more than 400 patients with the disease. But his experience with drug labeling and the FDA is less extensive. His most significant credential is that he served as the lead author of a citizen's petition filed with the FDA in 2005, after Bartlett's injuries, that resulted in the addition of a more explicit SJS/TEN warning to

NSAID labels. See Bartlett, 2010 DNH 112, at 15 n.6. In his capacity as a professor of plastic surgery, he also "instructs his students [on] how to review [drug] labels ... so that they can appropriately communicate warnings to their patients." Lofton, 2008 WL 4878066, at *9.

While Dr. Salisbury may not be the optimal witness for this type of case, another federal court recently concluded that "his extensive practical experience with SJS/TEN patients and the efficacy of warning labels in the clinical setting" qualified him to testify about the adequacy of an NSAID's label. Id. This court agrees. Dr. Salisbury falls in the same camp as Mutual's corresponding expert Dr. Stern: both of them clearly know more about SJS/TEN than about drug labeling, but nevertheless have enough knowledge and experience to testify about the adequacy of Sulindac's safety warning as it relates to SJS/TEN. See Part III.A.ix, supra. Mutual's request to exclude Drs. Tackett and Salisbury from testifying due to a lack of qualifications is therefore denied.

vi. Mutual's ethics and motives (Requests D.1.a, D.2)

Mutual argues that Drs. Tackett and Salisbury should be precluded from testifying about the ethics or morality of Mutual's decisions or about Mutual's motive or state of mind in making them. Bartlett concedes, in response, that "other than

state of mind as might plainly appear on a document or from deposition testimony," she will not "offer any opinions from Drs. Tackett or Salisbury on ethical obligations, state of mind, knowledge or intent." In light of that concession, which the court interprets to cover motive as well, Mutual's request to exclude such testimony is moot. Any remaining objections in this area that Mutual may have can be made at trial.

vii. Generic drug labeling (Requests D.1.a, D.2)

Mutual also seeks to preclude Drs. Tackett and Salisbury from testifying that if Mutual had attempted to strengthen Sulindac's safety warning, the FDA would have approved those changes based on the information in the medical literature. Such testimony is indeed speculative on this record, for reasons that this court explained in its recent summary judgment ruling, see Bartlett, 2010 DNH 112, at 15, and in denying Bartlett's analogous request to exclude Mutual's experts from speculating that the FDA would not have allowed such changes. See Part III.A.i, supra (citing In re Rezulin, 309 F. Supp. 2d at 550, which excluded an expert's "speculation as to what FDA might have done in hypothetical circumstances"). As such, it lacks a sufficient foundation to satisfy Rule 702. Mutual's request to exclude such testimony is granted.

viii. Sulindac's risk of SJS/TEN (Request D.1.b)

Next, Mutual argues that Bartlett's experts should not be allowed to suggest that Sulindac carries a higher risk of SJS/TEN than other NSAIDs or other drugs. Mutual argues that such testimony is speculative, because the available evidence on that point -- including, in particular, the adverse event data reported by Maja Mockenhaupt et al., The Risk of SJS and TEN Associated with NSAIDs: A Multinational Perspective, 30 Journal of Rheumatology 2234-2240 (Oct. 2003)) -- is largely anecdotal and not statistically significant. But Bartlett's experts acknowledged the limits of the data at their depositions, so this is really an issue for cross-examination, as opposed to outright exclusion. Moreover, a recently discovered draft of the study suggests that the data might be more extensive than is apparent from the published article. See document no. 251 (ordering supplemental depositions regarding that draft). Mutual's request to exclude testimony on this topic is denied.

Mutual also argues that Dr. Tackett should be prohibited from using information about Bactrim, another drug that Mutual manufactures and that has been linked to SJS/TEN, to support his opinion about what Mutual should have done with respect to Sulindac. Mutual argues that whether Bactrim creates a risk of SJS/TEN has no bearing on whether Sulindac creates such a risk and that, even it did, Mutual acquired Bactrim only one month or

so before Bartlett filled her prescription. But those issues also go to weight, not admissibility. Mutual's request to exclude such testimony is denied.

ix. Treating physicians (Request E)

Finally, Mutual seeks to exclude Bartlett's treating physicians from offering any expert testimony at trial, since they did not prepare expert reports pursuant to Fed. R. Civ. P. 26(a)(2)(B). Both parties agree, however, that "Rule 26(a)(2)(B) reports are not required as a prerequisite to a treating physician expressing opinions as to causation, diagnosis, [and] prognosis ... where they are based on the [plaintiff's] treatment," provided, as is the case with each doctor, that the witness has been properly designated as an expert under Rule 26(a)(2)(A). Sprague v. Liberty Mut. Ins. Co., 177 F.R.D. 78, 81 (D.N.H. 1998) (Muirhead, M.J.); see also Aumand v. Dartmouth Hitchcock Med. Ctr., 611 F. Supp. 2d 78, 87-89 (D.N.H. 2009). Bartlett has disavowed any intent to present testimony that goes beyond that scope.

To the extent that the parties may disagree about where the line should be drawn between "treatment" opinions and "non-treatment" opinions (which is not entirely clear from their briefing), those disagreements can be resolved at trial, in accordance with the basic principle set forth above. As a

general matter, Bartlett's treating physicians may testify about whether Sulindac caused Bartlett's injuries, provided that they reached that conclusion in a reliable manner while examining and treating Bartlett. See Sprague, 177 F.R.D. at 81. But they should not be asked "hypothetical question[s]" about causation that "include[] information not learned during the course of treatment." Vosburgh v. Bourassa, 2008 DNH 133, at 7-8 (McAuliffe, C.J.). Such opinions would render them "witness[es] ... retained or specially employed to provide expert testimony in the case," requiring expert reports under Fed. R. Civ. P. 26(a)(2)(B), which were not produced.

IV. Conclusion

As set forth above, Bartlett's motion to exclude or limit Mutual's expert testimony[5] is GRANTED in part and DENIED in part. Mutual's corresponding motion to exclude or limit Bartlett's expert testimony[6] is also GRANTED in part and DENIED in part.

SO ORDERED.

/s/Joseph N. Laplante
Joseph N. Laplante
United States District Judge

Dated: July 22, 2010

cc: Keith M. Jensen, Esq.

[5]Document no. 128.

[6]Document no. 142.

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